

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Aug 2026

### A clinical trial of comparing the effect of Albumin administration on urine output when using with lasix and mannitol with using lasix and mannitol without Albumin in oliguric patients in ICU

#### Protocol summary

##### Summary

The main objective of this study is investigating the effect of Albumin on urine output, using it with lasix and mannitol in ICU patients with oliguria. This is a clinical trial on 100 patients in ICU who are suffering from acute renal failure and oliguria. Sampling will done using availability sampling method of patients in ICUs of Bahonar hospital of Kerman. Inclusion criteria: oliguric patients in ICU; patients with Acute Renal Failure. Exclusion criteria: history of kidney disorders (Cr>1.5mg/dl); proteinuria (urine pr>3.5g/d); kidney disorders like glomerulonephritis and ATN; consumption of furosemide within last two weeks; incorrect urine collection; urine line blockage; low level of albumin (below 4.5 mg/dl). The subjects are divided into two groups of intervention and control using simple randomization by means of draw. In intervention group in addition of lasix and mannitol, Albumin is administered. In control group just lasix and mannitol are given. Central venous Pressure, superficial edema and the ratio of PAO2/FIO2 will be measured before commerce of diuresis and during therapeutic period. Urine output is measured every 6 hours. BUN and Cr are measured at the time of admission and then daily. Glomerular filtration rate (GFR) is measured before commerce of diuresis and after starting diuresis. finally the collected data will be analyzed according to the study's objectives.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016013010741N3**  
Registration date: **2016-04-28, 1395/02/09**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-04-28, 1395/02/09

##### Registrant information

###### Name

Minoo Ghahraman

###### Name of organization / entity

Kerman University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 34 1211 5814

###### Email address

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##### Recruitment status

###### Recruitment complete

##### Funding source

Kerman University of Medical Sciences

##### Expected recruitment start date

2015-04-21, 1394/02/01

##### Expected recruitment end date

2015-12-22, 1394/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

A clinical trial of comparing the effect of Albumin administration on urine output when using with lasix and mannitol with using lasix and mannitol without Albumin in oliguric patients in ICU

##### Public title

Investigating the effect of Albumin on urine output, using

it with lasix and mannitol in ICU patients with oliguria

#### **Purpose**

Treatment

#### **Inclusion/Exclusion criteria**

Inclusion criteria: oliguric patients in ICU; patients with Acute Renal Failure. Exclusion criteria: history of kidney disorders (Cr>1.5mg/dl); proteinuria (urine pr>3.5g/d); kidney disorders like glomerulonephritis and ATN; consumption of furosemide within last two weeks; incorrect urine collection; urine line blockage; low level of albumin (below 4.5 mg/dl).

#### **Age**

No age limit

#### **Gender**

Both

#### **Phase**

2

#### **Groups that have been masked**

No information

#### **Sample size**

Target sample size: 100

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Not blinded

#### **Blinding description**

#### **Placebo**

Not used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

##### **Ethics committee**

###### **Name of ethics committee**

Ethics Committee of Kerman University Medical Sciences

###### **Street address**

Kerman University Medical Sciences, Shafa Square

###### **City**

Kerman

###### **Postal code**

##### **Approval date**

2016-04-03, 1395/01/15

##### **Ethics committee reference number**

ir.kmu.rec.1394.710

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

Acute renal failure

#### **ICD-10 code**

N17.9

#### **ICD-10 code description**

Acute renal failure, unspecified

### **Primary outcomes**

#### **1**

##### **Description**

Serum BUN level

##### **Timepoint**

At the time of admission and then daily

##### **Method of measurement**

Blood test

#### **2**

##### **Description**

Serum Cr level

##### **Timepoint**

At the time of admission and then daily

##### **Method of measurement**

Blood test

### **Secondary outcomes**

#### **1**

##### **Description**

Daily urine output

##### **Timepoint**

During hospital stay daily

##### **Method of measurement**

Documentation of collected urine in 24 hours

#### **2**

##### **Description**

Glomerular filtration rate (GFR)

##### **Timepoint**

Every day during hospital stay

##### **Method of measurement**

By means of creatinine clearance equation

#### **3**

##### **Description**

CVP

##### **Timepoint**

Before commerce of diuresis and during therapeutic period

##### **Method of measurement**

Monitoring device

#### **4**

##### **Description**

Superficial edema

##### **Timepoint**

Before commerce of diuresis and during therapeutic period

**Method of measurement**

Examination

**Intervention groups****1****Description**

In intervention group in addition to mannitol and lasix (400 mg lasix plus 100 ml mannitol 20% administering 1 mg/kg/h for 2 consecutive days), albumin (one vial of albumin 20% in 1 litre normal saline 2 times a day for 2 consecutive days) is given.

**Category**

Treatment - Drugs

**2****Description**

In control group mannitol and lasix (400 mg lasix plus 100 ml mannitol 20% administering 1 mg/kg/h for 2 consecutive days) is given.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Bahonar Hospital

**Full name of responsible person**

Mehdi Ahmadinejad

**Street address**

Bahonar Hospital, Bagh-e-melli square

**City**

Kerman

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice chancellor for research, Kerman University of Medical Sciences

**Full name of responsible person**

Fatemeh Hassani

**Street address**

Tahmasbabad Square, Ebnesina Street

**City**

Kerman

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research, Kerman University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector***empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Minoo Ghahraman

**Position**

Anesthesiologist

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Maryam Farrokhhabadi

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MD, Resident of Anesthesiology

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*